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ID

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/084,491	05/27/98	MOORE P	PF378

022195
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HM12/0330

EXAMINER
SLOBODYANSKY,E

ART UNIT	PAPER NUMBER
1652	23

DATE MAILED: 03/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/084,491	Applicant(s) Moore et al.
	Examiner Elizabeth Slobodyansky	Group Art Unit 1652

☒ Responsive to communication(s) filed on *Jan 25, 2001* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *21-55, 57-70, 73, and 74* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21-55, 57-70, 73, and 74* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *21*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The amendment filed January 25, 2001 canceling claims 56 and 71 and amending claim 54 has been entered.

The Declaration of Drs. Moore, Ebner and Rosen filed on January 25, 2001 under 37 CFR 1.131 is sufficient to overcome the Du et al. reference.

Claims 21-55, 57-70, 73 and 74 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Specification

The specification is objected to because of the following. Figure 2 shows an alignment of t-PALP and human t-PA. SEQ ID NO:2 consisting of 263 amino acids is aligned with residues 191-516 of t-PA. On page 7, lines 9-10, the t-PA sequence is referred to as SEQ ID NO:3. SEQ ID NO:3 has 372 amino acids. Residues 191-516 of t-PA on Figure 2 correspond to residues 1-325 of SEQ ID NO:3. Correction should be made to make Figure 2 consistent with its description.

This objection is reiterated from the Office action mailed July 25, 2000.

In response to Applicant's Remarks (page 3, 1st paragraph), the examiner notes that 1.822 (d, 4) is not contradictory to the objection. Because applicants indicate the fragment as 191-516 of t-PA, the sequence of t-PA should be given. It is possible to amend the description of drawings by referring to as fragment 191-516 of t-PA (residues 1-325 in SEQ ID NO:3), for example.

Claim Rejections - 35 USC § 101

Claims 21, with dependent claim 22-55, claim 57, with dependent claims 58-70, and claims 73-74 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection has been explained in the Office action mailed July 25, 2000. In sum, there is no data in the specification to support function of SEQ ID NO:1.

Claims 21, with dependent claim 22-55, claim 57, with dependent claims 58-70, and claims 73-74 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

Claims 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising at least 30 and 50 nucleotides, respectively, of residues 630 to 750 of SEQ ID NO:1.

This rejection has been explained in the Office action mailed July 25, 2000.

Claims 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fragment consisting of at least 30 and 50 nucleotides of residues 630 to 750 of SEQ ID NO:1, respectively, does not reasonably provide enablement for a fragment comprising at least 30 and 50 nucleotides, respectively, of residues 630 to 750 of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection has been explained in the Office action mailed July 25, 2000.

Claim 74 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection has been explained in the Office action mailed July 25, 2000.

Claim 74 is dependent from claim 73. Claim 73 is drawn to a polynucleotide comprising at least 30 contiguous nucleotides. Claim 74 is drawn to a polynucleotide of claim 73 further comprising at least 50 contiguous nucleotides.

In response to Applicant's Remarks (paragraph bridging pages 11 and 12), the examiner agrees that the term "said nucleic acid" in claim 74 has an antecedent basis in claim 73. However, the word "further" renders the claim unclear.

Response to Arguments

Applicant's arguments filed January 25, 2001 have been fully considered but they are not persuasive.

Applicants argue that there is significant homology between SEQ ID NO:2 and t-PA. They refer to several pages in the specification and to Figure 2. The examiner did not find any reference to homology on the pages referred to by Applicants. The examiner considers homology shown on Figure 2 as low.

The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby.

The disclosed protein, whose cDNA has been isolated, is said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial credible utility might be found for the claimed isolated compositions. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant claims are drawn to a DNA encoding a protein of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the t-PALP of the instant application was, as of the filing date, useful for treatment of various pathological conditions as indicated by Applicants (paragraph bridging pages 4 and 5). Until some actual and specific significance can be attributed to the protein identified in the specification as t-PALP, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

Applicant assert that SEQ ID NO:2 has homology with the kringle domain (page 4, 2nd paragraph). The examiner notes that assuming that this is correct, such homology does not yet impart any specific function to the protein because the kringle domain is present not only in t-PA but in proteins of diverse functions such as

urokinase and Factor XII, for example. Therefore, the homology with the kringle domain, if it exists, is insufficient to predict the function of a protein. To employ a protein of the instant invention in any of the disclosed methods would clearly be using it as the object of further research. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for t-PALP, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

Regarding claims 73 and 74, Applicants argue that one skilled in the art "could readily envision countless polynucleotide sequences that comprise the specified polynucleotide" (paragraph bridging pages 7 and 8). While the sequences are countless their structure is not described and they may comprise any nucleotide sequence of any size. The function(s) of said "countless polynucleotide sequences" is not described and is unpredictable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

March 29, 2001